South Carolina
DHEC
Department of Health and Environmental Control
2600 Bull Street, Columbia, SC 29201

January 13, 1995

MEMORANDUM

TO: Hospital Administrators

FROM: Alan Samuels, Director
Division of Health Licensing

SUBJECT: Conditions which will allow provider-wide partial exceptions to the requirements of Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Sections 303. and 605.2.

R61-16, Section 303., requires that, "The medical staff, either as a whole or on a department or clinical service basis, shall meet at least once each month to review and analyze their clinical experience..." We have determined that an alternative standard will be acceptable. All hospitals will be required to meet either the standard outlined in R61-16, Section 303., or as alternative:

> The medical staff whether as a whole or on a department or clinical service basis, shall meet at least once every three months to review and analyze their clinical experience. Written minutes of medical staff meetings shall be maintained. The approach for scheduling medical staff meetings shall be outlined in hospital policies and procedures. Quality assurance must be an ongoing process, thus, procedures shall include a stipulation for meeting more frequently when such a need arises.

R61-16, Sections 605.2 and 605.2.2., require that, "There shall be written policies and procedures for the decontamination and sterilization activities...These policies and procedures shall relate, but are not limited to the following:...Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use..." R61-16, Section 605.5, requires that, "...Labels shall include at least the expiration date of the contents."

We have determined that the "event-related" methodology for determining sterile integrity of hospital-sterilized medical items is a generally accepted professional practice and an acceptable alternative to the "time related" methods outlined in current R61-16 standards. If a hospital desires to implement event related methods for determining shelf life of hospital-sterilized medical items then policies and procedures shall so indicate.

AS:DG:ms

cc: Douglas E. Bryant, Commissioner
Alice Truluck, Customer Service Liaison